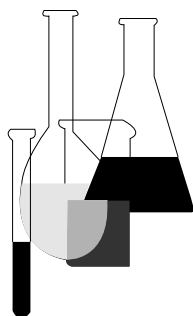




Ecological Effects Test Guidelines

OPPTS 850.3040 Field Testing for Pollinators



“Public Draft”

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading “Environmental Test Methods and Guidelines” or in paper by contacting the OPP Public Docket at (703) 305-5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202-512-0135 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading “Environmental Test Methods and Guidelines.”

OPPTS 850.3040 Field testing for pollinators.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 141–5 Field Testing for Pollinators (Pesticide Assessment Guidelines, Subdivision L—Hazard Evaluation; Nontarget Insects) EPA report 540/09-82-019, 1982.

(3) **Purpose.** This guideline is designed to develop data on pesticide hazards to bees under actual field conditions.

(b) **Test method**—(1) **Objective.** As this field test will be required only on a case-by-case basis and will be conducted in response to some specific problem, it may be designed to answer any number of questions concerning pesticide hazard to bees. These questions will be determined during consultation between the registrant and the Agency.

(2) **Method.** The study should satisfy the general test standards contained in OPPTS 850.1000, Background for Nontarget Organism Testing.

(i) **Test material.** The test material must be a typical end-use product.

(ii) **Test organisms.** Testing will be conducted on the species of concern. Pollinators of economic importance in the United States include the honey bee (*Apis mellifera*), alfalfa leafcutting bee (*Megachile rotundata*), and alkali bee (*Nomia melanderi*).

(iii) **Test conditions.** The test conditions for conducting an actual field test should resemble the conditions likely to be encountered under actual use of the product. Specifically, the pesticide should be applied to the site at the rate, frequency, and method specified on the label.

(iv) **Test protocol.** Information useful in developing a test protocol may be obtained from paragraphs (d)(1), (d)(2), and (d)(3) of this guideline. It should be noted, however, that any testing conducted to satisfy this requirement should be preceded by consultation with the Agency,

(c) **Data reporting.** The report should include, but not necessarily be limited to, the following information:

(1) Name and address of the facility performing the study and the dates of the study.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Information about the chemicals used should include:

(i) The test and, if used, control substances identified by name, Chemical Abstracts Service (CAS) number or code number, source, lot or batch number, strength, purity, and composition or other appropriate characteristics.

(ii) Vehicle used to dissolve or dilute the test substance, preparation methods, and any adjuvants used.

(ii) Amount of test material (per acre, per colony, etc.), method of administration, and rationale for selection of method, route, or frequency.

(4) A description of the test system used, including the scientific name and strain of the test species, number used, condition, age at test initiation, and source of test bees.

(5) A description of the dosages, numbers of bees and replicates per dose, and method and time of administration. The reported results should include the results of range-finding tests, if conducted, and for the definitive test, a description of signs of intoxication and other abnormal behavior, including time of onset, duration, severity, and number affected at each dose level and control.

(6) A description of the methods used, including:

(i) Number of treatment levels.

(ii) Number of bees per treatment level.

(iii) Method of assigning bees to treatment and control groups and method of assigning field plots.

(iv) Method used to determine treatment levels.

(v) Size of colonies or cages, and method of assigning bees to cages, if appropriate.

(vi) Number of bees per cage or colony.

(vii) Number of controls.

(viii) Type of controls.

(ix) Environmental conditions (ambient temperature, humidity, weather conditions, etc. during and after application).

(x) Source and availability of food and water.

(xi) Length of total observation period.

(xii) Frequency and duration of each observation.

(xiii) Criteria for determining effects.

(7) A description of all circumstances that may have affected the quality or integrity of the data.

(8) Statistical methods employed for analyzing the data, including a description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis. Results of the analysis of data should include the calculated LD50 value, 95 percent confidence limits, slope of the transformed dose-response line, and the results of a goodness-of-fit test.

(9) The name of the sponsor, study director, principal investigator, names of other scientists or professionals, and the names of all supervisory personnel involved in the study.

(10) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.

(11) The locations where all raw data and the final report are stored.

(12) The statement prepared and signed by the quality assurance unit.

(d) **References.** The following references should be consulted for additional background material on this test guideline.

(1) Atkins, E.L. et al. Protecting Honeybees from Pesticides. University of California, Division of Agricultural Sciences, Leaflet 2883, 14 pp. (1976).

(2) Robinson, W.S. and C.A. Johansen, Effects of Control Chemicals for Douglas Fir Tussock Moth *Orgyia pseudotsugata* (McDonnough) on Forest Pollination (Lepidoptera: Lymantriidae), *Washington State Entomological Society Melanderia* 30:9–56 (1978).

(3) U.S. Environmental Protection Agency, Standard Evaluation Procedure, Field Testing for Pollinators. Report Number EPA 540/09–86–140 (1986).